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| APPLICATION NO.        | FILING DATE                     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|------------------------|---------------------------------|----------------------|-------------------------|------------------|
| 10/511,525             | 10/15/2004                      | Hui-Fang Chang       | 100694-1P US            | 4565             |
| 22466                  | 7590 06/21/2006                 |                      | EXAMINER                |                  |
|                        | NECA PHARMACEUT                 | DESAI, RITA J        |                         |                  |
| GLOBAL IN<br>1800 CONC | NTELLECTUAL PROPERT<br>ORD PIKE | Υ                    | ART UNIT                | PAPER NUMBER     |
|                        | ON, DE 19850-5437               | 1625                 |                         |                  |
|                        |                                 |                      | DATE MAILED: 06/21/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)  |  |  |  |  |  |
|--|--|---|--|--|--|--|--|
| OSC Antino Communication   | 10/511,525   | CHANG ET AL.  |  |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |  |  |  |  |  |
|  | Rita J. Desai  | 1625  |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c   | orrespondence address   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | l. ely filed the mailing date of this communication. O (35 U.S.C. § 133). |  |  |  |  |  |
| Status   |  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on   |  |   |  |  |  |  |  |
|  | action is non-final.   |   |  |  |  |  |  |
| · <u> </u>   | , —  |   |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |   |  |  |  |  |  |
| Disposition of Claims  |  |   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-4 and 14-18</u> is/are pending in the application.   |  |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |   |  |  |  |  |  |
| 6) Claim(s) is/are rejected.   |  |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |   |  |  |  |  |  |
| 8) Claim(s) <u>1-4, 14-18</u> are subject to restriction ar  | d/or election requirement.   |   |  |  |  |  |  |
| Application Papers   |  |   |  |  |  |  |  |
| 9) The specification is objected to by the Examine   | <b>'</b> .   |   |  |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |  |   |  |  |  |  |  |
| Applicant may not request that any objection to the  | drawing(s) be held in abeyance. See  | e 37 CFR 1.85(a).   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correcti  | on is required if the drawing(s) is obj  | ected to. See 37 CFR 1.121(d).  |  |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Ex  | aminer. Note the attached Office   | Action or form PTO-152.   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:   | priority under 35 U.S.C. § 119(a)  | -(d) or (f).  |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |  |   |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |   |  |  |  |  |  |
| application from the International Bureau  | (PCT Rule 17.2(a)).  |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |   |  |  |  |  |  |
|  |  |   |  |  |  |  |  |
| Attachment(s)  |  |   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary   |   |  |  |  |  |  |
| 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   | Paper No(s)/Mail Da 5) Notice of Informal P  | atent Application (PTO-152)   |  |  |  |  |  |
| Paper No(s)/Mail Date  | 6)  Other:   |   |  |  |  |  |  |

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 18 and 19, drawn to compounds of formula I as given in claim 1.classified in class 546, subclass 18, 115.

II. Claims 14-17, drawn to method of treating, classified in class 514, subclass 278.The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the various method of treating the various diseases such as ulcerative colitis, craving, pain can be treated by other drugs available in the market. For e.g. pain can be treated by aspirin.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Thus the Inventions are Independent and Distinct and the search is burdensome to the PTO.

A telephone call was made to Mr. Mitchell on June 12, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder:-

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The examiner has required restriction between product and process claims. Where applicants elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to the final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, thus to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product or have all the limitations of the product claim.

Failure to do so may result in a loss of the right to rejoinder.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai Primary Examiner Art Unit 1625 Ble 6/16/06

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R.D.

June 16, 2006